Claims:

1. A pharmaceutical hydrogel formulation, comprising: (a) a therapeutically effective amount of a drug in (b) a hydrogel comprised of water and polyvinyl alcohol, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h and represents Y percent by weight of the hydrogel, wherein Y and D_h are selected to correspond to each other in a manner which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 5°C to 40°C.

2. The formulation of claim 1, wherein D_h is in the range of approximately 95% to 99.9% and Y is in the range of approximately 10 wt.% to 30 wt.%.

3. The formulation of claim 2, wherein D_h is in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt.% to 25 wt.%.

4. The formulation of claim 1, wherein syneresis is reduced or eliminated upon storage of the formulation for at least six months at a storage temperature in the range of approximately 20°C to 40°C.

5. The formulation of claim 1, wherein D_h is greater than about 97.5 wt.%, the hydrogel is prepared using a single-cycle freeze-thaw procedure, and Y is greater than or equal to approximately $5D_h$ - 479, but is less than the solubility of the polyvinyl alcohol in the hydrogel at the storage temperature.

6. The formulation of claim 1, wherein D_h is less than about 97.5 wt.%, the hydrogel is prepared using a multiple-cycle freeze-thaw procedure, and Y is greater than or equal to approximately $4.16D_h - 385$, but is less than the solubility of the polyvinyl alcohol in the hydrogel at the storage temperature.

7. The formulation of claim 1, being substantially free of polymeric materials other than polyvinyl alcohol.

8. The formulation of claim 1, wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 10,000 to 400,000.

9. The formulation of claim 8, wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 12,000 to 200,000.

10. The formulation of claim 9, wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 15,000 to 100,000.

11. The formulation of claim 1, in the form of a drug reservoir for electrotransport drug delivery.

12. The formulation of claim 1, in the form of a drug reservoir for passive transdermal drug delivery.

13. A drug delivery system comprising the formulation of claim 1 and a pharmaceutically acceptable carrier.

14. The drug delivery system of claim 13, wherein the carrier is suitable for oral administration, and the system is in the form of a capsule.

15. The drug delivery system of claim 13, wherein the carrier is suitable for topical, transdermal or transmucosal drug administration, and the system is in the form of an ointment, gel or cream.

16. The drug delivery system of claim 13, wherein the carrier is suitable for vaginal or rectal drug administration, and the system is in the form of a suppository.

17. The drug delivery system of claim 13, in the form of an aerosol spray.

18. The drug delivery system of claim 13, wherein the carrier is suitable for buccal drug administration, and the system comprises a buccal dosage form.

19. An electrotransport drug delivery device comprising:

a donor electrode, a counter electrode, and a source of electrical power adapted to be electrically connected to the donor electrode and the counter electrode, the donor electrode having a hydrogel drug reservoir connected thereto, wherein the reservoir is comprised of the pharmaceutical hydrogel formulation of claim 1.

20. An electrotransport drug delivery device comprising:

a donor electrode, a counter electrode, and a source of electrical power adapted to be electrically connected to the donor electrode and the counter electrode, the donor electrode having a hydrogel drug reservoir connected thereto,

wherein the reservoir is comprised of the pharmaceutical hydrogel formulation of claim 5.

21. An electrotransport drug delivery device comprising:

a donor electrode, a counter electrode, and a source of electrical power adapted to be electrically connected to the donor electrode and the counter electrode, the donor electrode having a hydrogel drug reservoir connected thereto, wherein the reservoir is comprised of the pharmaceutical hydrogel formulation of claim 6.

22. A method for eliminating syneresis in a pharmaceutical hydrogel formulation comprised of (a) a therapeutically effective amount of a drug in (b) a hydrogel comprised of water and polyvinyl alcohol, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h and represents Y percent by weight of the hydrogel, the method comprising selecting Y and D_h to correspond to each other in a manner which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 5°C to 40°C.

23. The method of claim 22, wherein D_h is in the range of approximately 95% to 99.9% and Y is in the range of approximately 10 wt.% to 30 wt.%.

24. The method of claim 23, wherein D_h is in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt.% to 25 wt.%.

25. The method of claim 22, wherein syneresis is reduced or eliminated upon storage of the formulation for at least six months at a storage temperature in the range of approximately 20°C to 40°C.

26. The method of claim 22, wherein D_h is greater than about 97.5 wt.%, the hydrogel is prepared using a single-cycle freeze-thaw procedure, and Y is greater than or equal to approximately $5D_h$ - 479, but is less than the solubility of the polyvinyl alcohol in the hydrogel at the storage temperature.

27. The method of claim 22, wherein D_h is less than about 97.5 wt.%, the hydrogel is prepared using a multiple-cycle freeze-thaw procedure, and Y is greater than or equal to approximately $4.16D_h$ - 385, but is less than the solubility of the polyvinyl alcohol in the hydrogel at the storage temperature.

28. The method of claim 22, wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 10,000 to 400,000.

29. The method of claim 28, wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 12,000 to 200,000.

30. The method of claim 29, wherein the polyvinyl alcohol has a viscosity average molecular weight in the range of approximately 15,000 to 100,000.

31. A method for making a pharmaceutical hydrogel formulation comprised of a therapeutically effective amount of a drug in a polyvinyl alcohol hydrogel, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis

D_h and represents Y percent by weight of the hydrogel, the method comprising the steps of:

(a) preparing an aqueous solution containing a predetermined amount of polyvinyl alcohol;

(b) combining a pharmaceutical formulation containing a therapeutically effective amount of a drug, with the aqueous solution prepared in step (a);

(c) freezing the solution of step (b) at a temperature below about 0°C; and

(d) thawing the frozen solution for a time period not exceeding five hours,

wherein the amount of polyvinyl alcohol in step (a) is selected such that Y and D_h correspond to each other in a manner which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 5°C to 40°C.

32. The method of claim 31, wherein step (d) is conducted for a time period not exceeding one hour.

33. The method of claim 31, wherein D_h is in the range of approximately 95% to 99.9% and Y is in the range of approximately 10 wt.% to 30 wt.%.

34. The method of claim 33, wherein D_h is in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt.% to 25 wt.%.

35. The method of claim 31, wherein D_h is greater than about 97.5 wt.%, the hydrogel is prepared using a single-cycle freeze-thaw procedure, and Y is greater than or equal to approximately $5D_h$ - 479, but is less than the solubility of the polyvinyl alcohol in the hydrogel at the storage temperature.

36. The method of claim 31, wherein D_h is less than about 97.5 wt.%, the hydrogel is prepared using a multiple-cycle freeze-thaw procedure, and Y is greater than or equal to approximately $4.16D_h$ - 385, but is less than the solubility of the polyvinyl alcohol in the hydrogel at the storage temperature.

37. A method for making a pharmaceutical formulation, comprising the steps of:

(a) preparing an aqueous solution containing a predetermined amount of polyvinyl alcohol to provide a polyvinyl alcohol hydrogel, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h and represents Y percent by weight of the hydrogel;

(b) removing excess water from the polyvinyl alcohol hydrogel, to yield a dried hydrogel; and

(c) adding an aqueous solution of a drug to the dried hydrogel of step (b),

wherein the amount of polyvinyl alcohol in step (a) is selected such that Y and D_h correspond to each other in a manner which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 5°C to 40°C.

38. A method for making a pharmaceutical formulation, comprising the steps of:

(a) preparing an aqueous solution containing a drug and a predetermined amount of polyvinyl alcohol, to provide a drug-containing hydrogel, wherein the polyvinyl alcohol has a predetermined degree of hydrolysis D_h and represents Y percent by weight of the hydrogel; and

(b) removing excess water from the drug-containing hydrogel provided in step (a) to provide a pharmaceutical formulation in the form of a drug-containing dried hydrogel,

wherein the amount of polyvinyl alcohol in step (a) is selected such that Y and D_h correspond to each other in a manner which provides for a stable hydrogel and reduces or eliminates syneresis upon storage of the formulation for at least six months at a storage temperature in the range of approximately 20°C to 40°C.

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